K021522

MAY 21 2002

Summary of Safety and Effectiveness

Lorenz Lactosorb® 1.5 mm x 4 mm Tap Free Screw

Submitter: Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, Florida 32218-2480

Establishment Registration: 1032347

Contact Person: Sheryl Malmberg
Regulatory Affairs
(904)-741-4400

Trade Name: Lorenz 1.5 x 4 mm Lactosorb® Tap Free Screw

Common or Usual Name: Resorbable Bone Screw

Classification Name: Screw, Fixation, Intraosseous (21 CFR 872.4880)

Device Classification: Class II

Device Product Code: DZL

Indications for Use:

The Lactosorb® Tap Free Screw is indicated for use in the following midface and craniofacial procedures.

A. General Indication: trauma procedures of the midface or craniofacial skeleton
Specific Indications:
1. Comminuted fractures of the naso-ethmoidal infraorbital areas
2. Comminuted fractures of the frontal sinus wall
3. Pediatric midface or craniofacial trauma
4. LeFort (I, II, II) fractures
5. Orbital floor fractures
6. Fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones.
7. Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones.

B. General Indication: reconstructive procedures of the midface or craniofacial Skeleton
   1. Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.)
   2. LeFort (I, II, II) osteotomies
   3. Tumor reconstruction in midface or craniofacial procedures
   4. Bone graft procedures in the midface or craniofacial skeleton
   5. Pediatric reconstructive procedures
   6. Reconstructive procedures of the craniofacial skeleton including: frontal. parietal, temporal, sphenoid, and occipital bones
   7. Craniotomy flap fixation

This system is not designed for use in the mandible and/or full load bearing procedures.

Device Description: The device is a screw having a non-threaded pin portion and a head portion. The Lactosorb® Tap Free Screw is designed with a slight helical groove that is cut into the major diameter. The head geometry, drive mechanism, major diameter, and tip geometry of the 1.5 x 4 mm Tap Free Screw is identical to that of the 1.5 x 4 mm Direct Drive Screw (K971870). The only difference between the two screws is the "thread" form.

Although the tap free screws are similar in design to the standard Lactosorb® direct drive screws (K971870), they function more like the Lactosorb® Push Screws (K002423). The push screws are designed with barbs that are pushed into a drilled hole that is slightly smaller than the diameter around the barbs. This press fit holds the push screw is place and provides adequate fixation. The tap-free screws are implanted by rotating the screws into a hole that is slightly smaller than the major diameter of the screws. The press fit between the implant and the hole provides the fixation.

Material: Lactosorb® (resorbable copolymer) – a polyester derivative of lactic and glycolic acids

Lactosorb® is made of 82% L-Lactide/18% Glycolide copolymer that degrades by hydrolysis into L-Lactic and glycolic acids. These hydrolytic products are then further degraded into carbon dioxide and water via the cellular Krebs cycle. Lactosorb® has been previously cleared by 510(k) notifications for use in bone plates (K992355, K992158, K971870, K960988, K955729) and bone screws (K002423, K981666, K960988) for cranial and maxillofacial use.

The modifications made to this device are not anticipated to significantly affect its safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2002

Ms. Sheryl Malmberg
Walter Lorenz Surgical, Incorporated
1520 Tradeport Drive
Jacksonville, Florida 32218-2480

Re: K021522
Trade/Device Name: Lorenz 1.5 mm x 4.0 mm Lactosorb® Tap Free Screw
Regulation Number: 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: May 08, 2002
Received: May 10, 2002

Dear Ms. Malmberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K021522

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021522

~~(Optional Format~~ 1-2-96)

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